

Application No. 09/553,573
Amendment dated July 14, 2005
Reply to Office Action of March 14, 2005

REMARKS

Applicant cancelled claims 9, 10, 39, and 136 without prejudice or disclaimer of their subject matter, and amended claims 1, 102, and 147 to further define Applicant's claimed invention. The amendment to claim 1 is supported at least by claim 10 as originally filed. The amendment to claims 102 and 147 is supported at least by Fig. 9 as originally filed.

The Examiner objected to the amendment to the specification filed September 11, 2002 under 35 U.S.C. § 132 as introducing new matter. Applicant respectfully traverses the objection. The new paragraph added to the specification on page 17, after line 6 is supported at least by claim 39 as originally filed, which states that the opposed portions are "in moveable relationship to each other to allow for relative motion of the adjacent vertebral bodies after said implant is installed." Applicant respectfully brings to the Examiner attention that according to MPEP § 2163(I)(B), "[t]he claims as filed in the original specification are part of the disclosure...." (MPEP § 2163(I)(B) (May 2004); see also, MPEP § 608.01(I) "Original Claims" (May 2004)). Nonetheless, in order to expedite prosecution of the above-identified application, Applicant deleted the paragraph added to the specification in the amendment dated September 11, 2002, thus rendering the Examiner's objection moot.

The Examiner rejected claims 39 and 136 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Applicant traverses the Examiner's rejection. Applicant submits that the subject matter of claims 39 and 136 comply with the enablement requirement of 35 U.S.C. § 112, first paragraph. The concept of relative motion is discussed in Applicant's specification where it is disclosed that motion preserving implants "are adapted to allow for relative motion between the vertebrae" and "maintain the spacing between the two adjacent vertebral bodies." (See Specification, page 2, lines 14-17 and page 3, lines 1-5). Accordingly, Applicant submits that the subject matter of claims 39 and 136 is fully enabled as would be recognized by one skilled in the pertinent art. Nonetheless, in order to expedite prosecution of the present application, Applicant cancelled claims 39 and 136 without

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prejudice or disclaimer of their subject matter, thus rendering the Examiner's rejection moot.

The Examiner rejected claims 8, 9, and 39 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. For claims 8 and 9 in particular, the Examiner contends that "[i]t is unclear how applicant is forming a demarcation and how a single figure can show both 'less than half' and 'more than half.'" (Office Action, page 2, paragraph 4).

For the Examiner's rejection of claim 8, Applicant respectfully submits that the language of this claim is clear. Applicant respectfully submits that a person of ordinary skill in the art would understand the demarcation being formed by the plane dividing the implant into upper and lower halves, and that a reference line perpendicular to the mid-longitudinal axis may exist in the plane and serve as a reference from which the other elements of the claim are defined. The perpendicular line and the plane dividing the implant into upper and lower halves was illustrated by Applicant in Exhibit B of Applicant's reply dated April 23, 2004 (the "April 2004 Reply"). In response to the Examiner's request for a diagram, attached hereto is a copy of Exhibit B further annotated by Applicant.

As shown in Exhibit B, and identified by the number "8," less than half of leading end 102 of implant 100 is along the dotted line perpendicular to mid-longitudinal axis MLA. In particular, a small portion of leading end 102 is along the dotted line at the far left of the figure (where "8" points to). The rest of the leading end curves away from the dotted line and is not "along a line perpendicular to the mid-longitudinal axis of the implant" as recited in claim 8. Applicant submits that the rejection of claim 8 under 35 U.S.C. § 112, second paragraph, has been overcome.

For the Examiner's rejection of claim 9 under 35 U.S.C. § 112, second paragraph, Applicant traverses the Examiner's rejection and respectfully submits that the language of claim 9 is clear. Exhibit B, reference number "9," illustrates the implant having a leading end where more than half the leading end "is a curve that extends

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from said exterior side wall toward the mid-longitudinal axis of said implant in a plane dividing said implant into an upper half and a lower half." In particular, the portion of leading end 102 shown in Fig. 9 next to the series of small "x"s is an example of a curve that extends from the exterior side wall toward the mid-longitudinal axis. This portion of the leading end has a longer distance than the portion of the leading end extending from the interior side wall toward the mid-longitudinal axis. Accordingly, more than one half of leading end 102 exists on the right side of the mid-longitudinal axis due to the longer curve between the exterior side wall and the mid-longitudinal axis. Nonetheless, in order to expedite prosecution of the present application, Applicant cancelled claim 9 without prejudice or disclaimer of its subject matter, thus rendering the Examiner's rejection of claim 9 moot.

Applicant traversed the Examiner's rejection of claim 39 under 35 U.S.C. § 112, second paragraph, in the April 2004 Reply. The Examiner did not address Applicant's remarks from the April 2004 Reply. Applicant submits that the remarks from the April 2004 Reply still apply and overcome the Examiner's rejection. Nonetheless, in order to expedite prosecution of the present application, Applicant cancelled claim 39 without prejudice or disclaimer of its subject matter, thus rendering the Examiner's rejection of claim 39 moot.

The Examiner rejected claims 1-2, 4-34, 36-42, and 101-174 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,113,638 to Williams et al. ("Williams") in view of U.S. Patent No. 5,192,327 to Brantigan ("Brantigan"). Applicant respectfully traverses the Examiner's rejection. Independent claim 1 recites an artificial spinal implant with a hollow interior "having a maximum dimension between said inner surfaces of said interior and exterior facing side walls and in a plane perpendicular to the mid-longitudinal axis of said openings greater than said maximum dimension of said opening." Williams teaches a pair of hemi-oval devices 30, 32 having anchoring elements for introduction into the endplates of the adjacent vertebral bodies. (Williams, col. 5, line 51 to col. 6, line 4; Fig. 2). Brantigan teaches a hemi-oval device 20 having "opposed side walls 21a, a rounded oval end wall 21b, a flat opposite end wall 21c and

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a central aperture 21d." (Brantigan, col. 4, lines 57-64; Fig. 2). Neither Williams nor Brantigan, whether alone or in proper combination, teach or suggest a hollow interior with a dimension as recited in independent claim 1 of Applicant's claimed invention. In Brantigan, the maximum dimension of the hollow interior between the inner surfaces of the walls in a plane perpendicular to the mid-longitudinal axis of central opening 21d is the same as the maximum dimension of central opening 21d. (See Brantigan, Fig. 2).

Independent claims 102 and 147, as now amended, recite an artificial spinal implant having interior and exterior facing side walls, "said exterior facing side wall including a straight portion along the length of said implant." Neither Williams nor Brantigan, whether alone or in proper combination, teach or suggest the exterior facing side wall having a straight portion as recited in claims 102 and 147. The exterior facing side wall in Williams is entirely curved along the length of the device. (See Williams, Fig. 2). Wall 21b of the Brantigan device is also entirely curved along the length of the device. (See Brantigan, Fig. 2). Accordingly, Applicant respectfully submits that the Examiner's rejection of claims 1-2, 4-34, 36-42, and 101-174 under 35 U.S.C. § 103(a) as being unpatentable over Williams in view of Brantigan has been overcome.

The Examiner also rejected claims 1-2, 4-34, 36-42, and 101-174 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,609,635 to Michelson ("Michelson '635") in view of U.S. Patent No. 4,349,921 to Kuntz ("Kuntz").

Independent claim 1, as now amended, recites an artificial spinal implant having a leading end "being curved from said exterior side wall to beyond the mid-longitudinal axis of said implant." Neither Michelson '635 nor Kuntz, whether alone or in proper combination, teach or suggest a leading end having a curve as recited in independent claim 1 of Applicant's claimed invention. (See, e.g., Michelson, Fig. 1, insertion end 120; and Kuntz, Figs. 7-10).

Applicant respectfully traverses the Examiner's rejection of independent claims 102 and 147, and dependent claims 103-140, 144-146, 148-168, and 172-174 under 35 U.S.C. § 103(a) as being unpatentable over Michelson '635 in view of Kuntz. Applicant

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respectfully submits that the combination of Michelson '635 and Kuntz is untenable and cannot be maintained at least for the reasons stated below.

A. The motivation used to support the combination of references is inapplicable.

Applicant respectfully submits that the motivation used to support the combination of Michelson '635 with Kuntz is inapplicable. The Examiner states in the Office Action that "[i]t would have been obvious to one having ordinary skill in the art to have used the teachings of Kuntz forming a spinal implant in two halves with any vertebrae prosthesis including that of Michelson because *'when a prosthesis for the lumbar [sic] area is required, it has been found advantageous to make the prosthesis in two halves.'*" (Office Action, paragraph bridging pages 6-7). Applicant respectfully submits that the Examiner's asserted motivation is inapplicable because Michelson '635 already accomplishes without modification what the Examiner states is the reason to combine the teachings of Michelson '635 with Kuntz, i.e., "forming a spinal implant in two halves." Michelson '635 teaches the use of modular implants 400 that are inserted separately into the disc space. In particular, Michelson '635 teaches that "implant 400 has a width W that is substantially less than the width of the implants 100-300 such that a series of such implants 400 are used as the interbody spinal implant, each placed closely adjacent to one another to approximate the size of the removed disc." (Michelson, col. 10, lines 9-13; and Fig. 18). Accordingly, Applicant submits that one skilled in the art would not look to another reference for a teaching on forming a spinal implant in two halves when this feature is already taught by Michelson '635. (See MPEP § 2143.01, "the Prior Art Must Suggest the Desirability of the Claimed Invention" (May 2004)).

Under the "Response to Arguments" section of the Office Action, the Examiner acknowledges that Michelson '635 teaches modular implants and notes that "the teaching that their insertion end may be bullet shape or a convexity", see column 10, lines 35 et seq." (Office Action, paragraph bridging pages 2-3). Applicant respectfully submits that the further teachings of the shape of the leading end of the modular Implants of Michelson '635 is irrelevant to the Examiner's asserted motivation to form "a

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spinal implant into two halves" since "it has been found advantages [sic] to make the prosthesis in two halves," because the advantage stated by the Examiner is independent of the shape of the leading ends of the implants. As noted by Applicant above, Michelson '635 already teaches forming a spinal implant in two halves. Applicant respectfully submits that the Examiner's asserted motivation is inapplicable because Michelson '635 already teaches what the Examiner states as the reason for combining the teachings of Michelson '635 with the teachings of Kuntz.

B. Kuntz teaches away from Michelson '635.

Under the "Response to Arguments" section of the Office Action, the Examiner states that "[i]n response to applicant's arguments, section B, against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references." (Office Action, paragraph 1, page 3). Contrary to the Examiner's contention, Applicant has not attacked the references individually. Applicant referred to portions of Michelson '635 and Kuntz that demonstrate that the references teach away from one another. As set forth by the MPEP, references cannot be combined where the references teach away from one another. (MPEP § 2145(X)(D)(2) (May 2004)). Applicant's remarks on this point stand unchallenged by the Examiner and are repeated below.

Applicant further submits that the proposed combination of Michelson '635 with Kuntz is untenable because Kuntz teaches away from the implant of Michelson '635. Michelson '635 teaches an implant having openings 115 that "provide for bone growth to occur from the vertebrae through the openings 115 to the internal chamber 116." (Michelson '635, col. 6, lines 59-61). Kuntz teaches a spinal spacer that preserves some flexibility of the spinal joint. (Abstract, lines 1-4). Kuntz does not disclose a spinal fusion implant and in fact explicitly teaches away from spinal fusion. According to Kuntz, implants that permit tissue ingrowth are disadvantageous and "dangerous" because of problems related to bacterial infection, susceptibility for repeated injury, difficulty in removal of the prosthesis, spinal cord compression, and dysphagia. (See Kuntz, col. 1, line 67 to col. 2, line 24).

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Kuntz teaches that encapsulation of a solid implant is better than bone ingrowth into the surface of a porous implant because should the prosthesis become infected, the removal of an encapsulated implant would be "relatively simple." (Kuntz, col. 6, lines 48-54). The teaching away from porous implants is an essential feature of the prosthesis taught by Kuntz. Accordingly, Applicant submits that Kuntz teaches away from the disclosure of Michelson '635. (See MPEP § 2145(X)(D)(2), "References Cannot Be Combined Where Reference Teaches Away from Their Combination" (May 2004)).

C. The proposed combination still does not yield Applicant's claimed invention as recited in many of the claims.

Both independent claims 1 and 102 recite an implant having a third distance as measured from the junction of the leading end and the interior side wall to the plane perpendicular to and bisecting the length along the mid-longitudinal axis of the implant that is greater than a second distance as measured from the perpendicular plane to the junction of the leading end and the exterior side wall. Applicant submits that even if the combination of Michelson '635 and Kuntz could be properly maintained, the combination would still fail to result in an implant having a leading end with a third distance that is greater than the first and second distances, respectively as recited in independent claim 102. (See, Michelson '635, Fig. 2, leading end 120; and Kuntz, Figs. 7-10). The combination also does not yield an implant where the first distance is greater than the third distance as recited in claim 2, where the third distance is substantially greater than the first distance as recited in claim 5, where the trailing end is generally symmetrical relative to the mid-longitudinal axis as recited in claims 166, 169, and 172, and the relationships concerning the radius of curvature of the leading and trailing ends as recited in claims 167, 168, 170, 171, 173, and 174.

Independent claim 1, as now amended, recites an artificial spinal implant having a leading end "being curved from said exterior side wall to beyond the mid-longitudinal axis of said implant." As set forth above, neither Michelson '635 nor Kuntz, whether alone or in proper combination, teach or suggest a leading end being curved beyond

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the mid-longitudinal axis as recited in independent claim 1 of Applicant's claimed invention. (See, e.g., Michelson, Fig. 1, insertion end 120; and Kuntz, Figs. 7-10).

Independent claim 147 recites an artificial spinal implant having "a minimum length as measured from said leading end to said trailing end so that said leading end and said trailing end of said implant are adapted to rest upon portions of the apophyseal rim when implanted." Neither Michelson '635 nor Kuntz teach or suggest, whether alone or in proper combination, an implant as recited in claim 147.

Under the "Response to Arguments" section of the Office Action, the Examiner states that "[r]egarding applicant's arguments, section C, the combination which divides the implant of Michelson in half does produce an implant with a first distance greater than the second distance because of the actuate [sic] configuration of Michelson." (Office Action, paragraph 2, page 3). Applicant believes the Examiner's remarks refer to Applicant's remarks on page 32 of the April 2004 Reply, where Applicant stated that "[t]he combination also does not yield an implant where the first distance is greater than the second distance as recited in claim 2." Applicant respectfully submits that Applicant's remarks concerning claim 2 was made in error as claim 2 recites "wherein said first distance is greater than said third distance." Nonetheless, Applicant submits that the combination of Michelson '635 and Kuntz does not yield an implant where the first distance is greater than the third distance as recited in claim 2. Applicant notes that the remarks in Section C of the April 2004 Reply regarding claims 3, 5, 102, and 147 stand unchallenged by the Examiner.

Applicant submits that independent claims 1, 102, and 147 are patentable and that dependent claims 2-34, 36-42, 101, and 103-174 dependent from one of independent claims 1, 102, and 147, or claims dependent therefrom, are patentable at least due to their dependency from an allowable independent claim.

In view of the foregoing remarks, it is respectfully submitted that the claims, as amended, are patentable. Therefore, it is requested that the Examiner reconsider the outstanding rejections in view of the preceding comments. Issuance of a timely Notice of Allowance of the claims is earnestly solicited.

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To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this reply, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-1068.

Respectfully submitted

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